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## BY COURIER

The Commissioner of Patents  
and Trademarks,  
Washington, D.C.  
U.S.A. 20231

Dear Sirs:

**Re: U.S. Application No. 09/857,305**  
**Applicant: Robert C. Brunham et al**  
**Title: TWO-STEP IMMUNIZATION PROCEDURE**  
**AGAINST CHLAMYDIA INFECTION**  
**Filed: December 2, 1999**

Further to the Information Disclosure Statement submitted in August 21, 2001, submitted herewith are copies of the references asterisked in the Information Disclosure Statement listing and indicated to follow. The item indicated by asterisk will follow shortly.

Yours very truly,

  
\_\_\_\_\_  
Michael I. Stewart  
Registration No. 24,973

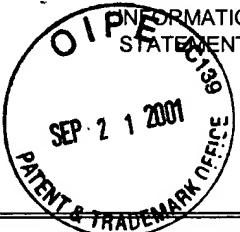
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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 1038-1153 MIS:ac	SERIAL NO.: 09/857,305
<b>O I P E</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> 		APPLICANT: Robert C. Brunham, et al.	
		FILING DATE December 2, 1999	GROUP ---

**U.S. PATENT DOCUMENTS**

*INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCL.	FILING DATE
	5,770,714	23/06/98	Agabian et al	536	23.1	
	5,389,368	14/02/95	Gurtiss, III			
	5,629,167	13/04/97	Ratti			
	5,869,608	09/02/99	Caldwell et al			
	6,024,961	15/02/00	Curtiss, III et al			
	6,001,372	14/12/99	DeMars et al			

**FOREIGN PATENT DOCUMENTS**

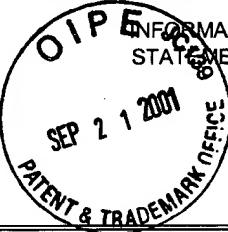
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCL.	TRANSLATION
	EP 0192033	27/08/86	EPO			YES NO
	WO 98/10789	19/03/98	PCT			
	WO 98/02546	22/01/98	PCT			
	WO 97/06263	20/02/97	PCT			
	WO 95/12411	05/11/95	PCT			
	WO 94/26900	24/11/94	PCT			
	WO 94/21291	09/29/94	PCT			
	WO 98/48026	29/10/98	PCT			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

1	Grayston, J.T. and S.-P. Wang. 1975. New knowledge of chlamydiae and the diseases they cause. <i>J. Infect. Dis.</i> , 132: 87-104.
2	Grayston, J.T., S.-P. Wang, L.-J. Yeh, and C.-C. Kuo. 1985. Importance of reinfection in the pathogenesis of trachoma. <i>Rev. Infect. Dis.</i> 7:717-725.
3	Taylor, H.R., et al., 1982. Animal Model of Trachoma. II. The importance of repeated infection. <i>Invest. Ophthalmol. Visual. Sci.</i> 23:507-515.
4	Taylor, H.R., et al. 1981. An Animal Model for Cicatrizing Trachoma. <i>Invest. Ophthalmol. Sci.</i> 21:422-433.
5	Caldwell, H.D., et al. 1987. Tear and serum antibody response to <i>chlamydia trachomatis</i> antigens during acute chlamydial conjunctivitis in monkeys as determined by immunoblotting. <i>Infect. Immun.</i> 55:93-98.
6	Wang, S.-P., et al., 1985. Immunotyping of <i>Chlamydia trachomatis</i> with monoclonal antibodies. <i>J. Infect. Dis.</i> 152:791-800.

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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 1038-1153 MIS:ac	SERIAL NO. 09/857,305
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	7	Nichols, R.L., et al., 1973. Immunity to chlamydial infections of the eye. VI. Homologous neutralization of trachoma infectivity for the owl monkey conjunctivae by eye secretions from humans with trachoma. J. Infect. Dis. 127:429-432.	
	8	Orenstein, N.S., et al., 1973. Immunity to chlamydial infections of the eye V. Passive transfer of antitrachoma antibodies to owl monkeys. Infect. Immun. 7:600-603.	
	9	Ramsey, KH, et al., (Mar. 1991) Resolution of Chlamydia Genital Infection with Antigen-Specific T--Lymphocyte Lines. Infect. and Immun. 59:925-931.	
	10	Magee, DM, et al., (1995). Role of CD8 T Cells in Primary <i>Chlamydia</i> Infection. Infect. Immun. Feb. 1995. 63:516-521.	
	11	Su, H. and Caldwell, HD., (1995) CD4+ T Cells Play a Significant Role in Adoptive Immunity to <i>Chlamydia trachomatis</i> Infection of the Mouse Genital Tract. Infect. Immun. Sept. 1995, 63: 3302-3308.	
	12	Beatty, PR., and Stephens RS., (1994) CD8+ T Lymphocyte-Mediated Lysis of <i>Chlamydia</i> -Infected L Cells Using an Endogenous Antigen Pathway., Journal of Immun. 1994, 153:4588.	
	13	Starnbach, MN., Bevan, MJ. and Lampe, MF. (1994), Protective Cytotoxic T. Lymphocytes are Induced During Murine Infection with <i>Chlamydia trachomatis</i> , Journal of Immun. 1994, 153:5183-5189.	
	14	Starnbach, MN, Bevan, MJ. And Lampe, MF., (1995), Murine Cytotoxic T. Lymphocytes Induced Following <i>Chlamydia trachomatis</i> Intraperitoneal or Genital Tract Infection Respond to Cells Infected with Multiple Serovars., Infect. & Immun. Sept. 1995, 63:3527-3530.	
	15	Igietseme, JU, (1996), Molecular mechanism of T-cell control of <i>Chlamydia</i> in mice: role of nitric oxide <i>in vivo</i> . Immunology 1996, 88:1-5.	
	16	Igietseme. JU, (1996), The Molecular mechanism of T-cell control of <i>Chlamydia</i> in mice; role of nitric oxide. Immunology 1996, 87:1-8.	
	17	Ward, M.E. 1992. Chlamydial vaccines – future trends. J. Infection 25, Supp. 1:11-26.	
	18	Caldwell, H.D., et al., (1981). Purification and partial characterization of the major outer membrane protein of <i>Chlamydia trachomatis</i> . Infect. Immun. 31:1161-1176.	
	19	Bavoil, P., Ohlin, A. and Schachter, J., (1984) Role of Disulfide Bonding in Outer Membrane Structure and Permeability in <i>Chlamydia trachomatis</i> . Infect. Immun., 44: 479-485.	
	20	Campos, M., et al., (1995) A <i>Chlamydia</i> Major Outer Membrane Protein Extract as a Trachoma Vaccine Candidate., Invest. Ophthalmol. Vis. Sci. 36:1477-1491.	
	21	Zhang Y.-X., et al., (1989). Protective monoclonal antibodies to <i>Chlamydia trachomatis</i> serovar- and serogroup-specific major outer membrane protein determinants. Infect. Immun. 57:636-638.	
	22	Zhang, Y.-X., et al., 1987. Protective monoclonal antibodies recognise epitopes located on the major outer membrane protein of <i>Chlamydia trachomatis</i> . J. Immunol. 138:575-581.	
EXAMINER:		DATE CONSIDERED:	

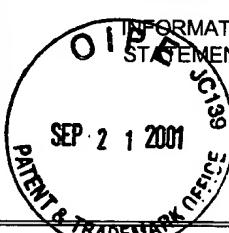
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
23	Department of Health and Human Services, (1989) Nucleotide and amino acid sequences of the four variable domains of the major outer membrane proteins of <i>Chlamydia trachomatis</i> . Report Nos: PAT-APPL-7-324664. National Technical Information Services, Springfield, VA.		
24	Yuan, Y., et al. (1989) Nucleotide and deduced amino acid sequences for the four variable domains of the major outer membrane proteins of the 15 <i>Chlamydia trachomatis</i> serovars. Infect. Immun. 57:1040-1049.		
25	Su, H. and Caldwell, H.D. 1992. Immunogenicity of a chimeric peptide corresponding to T-helper and B-cell epitopes of the <i>Chlamydia trachomatis</i> major outer membrane protein. J. Exp. Med. 175:227-235.		
26	Su, H., N.G. Watkins, Y.-X. Zhang and H.D. Caldwell (1990). <i>Chlamydia trachomatis</i> -host cell interactions: role of the chlamydial major outer membrane protein as an adhesin. Infect. Immun. 58:1017-1025.		
27	Peeling, R., I.W. McClean and R.C. Brunham. (1984). <i>In vitro</i> neutralization of <i>Chlamydia trachomatis</i> with monoclonal antibody to an epitope on the major outer membrane protein. Infect. Immun. 46:484-488.		
28	Lucero, M.E. and C.-C. Kuo. (1985). Neutralization of <i>Chlamydia trachomatis</i> cell culture infection by serovar specific monoclonal antibodies. Infect. Immun. 50:595-597.		
29*	Baehr, W., et al. (1988) Mapping antigenic domains expressed by <i>Chlamydia trachomatis</i> major outer membrane protein genes. Proc. Natl. Acad. Sci. USA, 85:4000-4004.		
30	Stephens, R.S., et al. (1988) High-resolution mapping of serovar-specific and common antigenic determinants of the major outer membrane protein of <i>Chlamydia trachomatis</i> . J. Exp. Med. 167:817-831.		
31	Conlan, J.W., I.N. Clarke and M.E. Ward. (1988). Epitope mapping with solid-phase peptides: Identification of type-, subspecies-, species-, and genus-reactive antibody binding domains on the major outer membrane protein of <i>Chlamydia trachomatis</i> . Mol. Microbiol. 2:673-679.		
32	Conlan, J.W., et al., (1990). Isolation of recombinant fragments of the major outer membrane protein of <i>Chlamydia trachomatis</i> : their potential as subunit vaccines. J. Gen. Microbiol. 136: 2013-2020		
33	Morrison, R.P., D.S. Manning, and H.D. Caldwell. (1992). Immunology of <i>Chlamydia trachomatis</i> infections. p. 57-84 In T.C. Quinn (ed) Sexually transmitted diseases. Raven Press Ltd., NY.		
34	Kersten, G.F.A. and Crommelin, D.J.A. (1995). Liposomes and ISCOMs as vaccine formulations. Biochimica et Biophysica Acta 1241 (1995) 117-138.		
35	Morein, B., et al., (1990) The iscom - a modern approach to vaccines seminars in Virology, Vol. 1, 1990: pp. 49-55.		
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 <b>O I S T A T E M E N T B Y A P P L I C A N T</b> <b>JC136</b> <b>SEP 21 2001</b> <b>PATENT &amp; TRADEMARK OFFICE</b>		<b>APPLICANT:</b> Robert C. Brunham, et al.		
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>				
36	Mowat & Reid, 1992. Preparation of Immune Stimulating Complexes (ISCOMs) as Adjuvants. Current Protocols in Immunology 1992. Supplement 4: 2.11.1. to 2.11.12.			
37	M.A. Liu et al. 1995. Ann. N.Y. Acad. Sci. 772.			
38	W.M. McDonnell and F.K. Askari 1996. N. Engl. J. Med. 334:42-45.			
39	J.B. Ulmer et al. 1993. Science 259:1745-1749.			
40	M. Sedegah et al. 1994. Proc. Natl. Acad. Sci. U.S.A. 91:9866.			
41	A. Darji et al. 1997. Cell 91:765-775.			
42	D.R. Sizemore, 1997. Vaccine 15:804-807.			
43	D. O'Callaghan and A. Charbit. 1990. Mol. Gen. Genet. 223:156-158.			
44	R. Brunham et al. 1994. J. Clin. Invest. 94:458-463.			
45	R.P. Morrison et al. 1995. Infect. Immun. 63:4661-4668.			
46	K.Y. Leung et al., 1991, PNAS 88(24):1147-4.			
47	Hayes L.J. et al., Journal of General Microbiology (1991), 137, 1557-1564.			
48	Boslego W.J. & Deal D.C. Gonorrhea Vaccines pp. 211-224.			
49	Ellis W. Ronald (Plotkin & Mortimer) Technologies for Making Vaccines. pp. 568-575.			
50	American Society for Microbiology May 1989. Abstracts of the Annual Meeting.			
51	Taylor H.R. et al., Oral Immunization Against Chlamydial ... 1987, Vol. 28, pp. 249-258			
52	Rank G.R. et al., Investigation Ophthalmology & Visual Science 1995., Vol. 36, pp. 1344-1351.			
53	Rank G.R. et al., Infection and Immunity 1990. p. 2599-2605.			
54	Myers G., Sriprakash S.K. Chlamydia Trachomatis DNA Encodes Homologues of Salmonella. Biology 40.			
55	Holst O.; Thomas-Oates E.J.; Brade H. Fur. J. Biochem. 222, 183-194 (1994)			
56	Evans D J; Minor P D; Almond J W. J.Appl.Bacteriol. (69,6,xiii) 1990.			
57	Brade L. et al., Infection and Immunity . 1987, p. 482-486.			
58	Ferris S., Antibody responses to the major outer membrane protein of chlamydia trachomatis. P.1-115			
59	May W.S., Cloning, sequencing and expression of the major outer membrane protein (MOMP) genr of feline chlamydia psittaci and evaluation of the immunogenicity of recombinant momp in mice.			
60	Peterson M.E. Infection and Immunity 1996, p. 3354-3359.			
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